UNITED STATES PATENT AND TRADEMARK OFFICE

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In re: Patent Term Extension
Application for
U.S. Patent No. 6,034,267

NOTICE OF FINAL DETERMINATION -- INELIGIBLE

An application for extension of the patent term of U.S. Patent No. 6,034,267 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on September 22, 2004. The application was filed by PhotoCure ASA, the patent owner of record. Extension is sought based upon the premarket review under § 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a human drug product known by the tradename METVIXIA™ having the active ingredient methyl aminolevulinate hydrochloride. METVIXIA™ was approved for commercial use and sale by the Food and Drug Administration (FDA) on July 27, 2004.

A determination has been made that U.S. Patent No. 6,034,267 is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of METVIXIA™.

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. 1.136. See 37 C.F.R. 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

The FDA official records indicate that LEVULAN® was previously approved for commercial marketing or use prior to the approval of METVIXIA™. In a letter dated March 5, 2007, FDA stated:

> A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that it does not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd. 894 F. 2d 392 (Fed. Cir. 1990). The active ingredient in Metvixia, methylaminolevulinate hydrochloride, is an ester of aminolevulinic acid hydrochloride, an active ingredient that has been previously approved for commercial marketing or use as Levulan, NDA 20-965.

Under 35 U.S.C. § 156(a) a term of a patent which claims a product shall be extended if, *inter alia*, the product has been subject to a regulatory review period before its commercial

marketing or use. In addition, under § 156(a)(5)(A):

> the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; (Emphasis added)

Thus, the determination of eligibility of U.S. Patent No. 6,034,267 turns on the provisions in § 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product. The term "product" is defined in 35 U.S.C. § 156(f) as follows:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the active ingredient of -
> (A) A new drug, antibiotic drug, or human biological product . . . .including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. (Emphasis added.)

By the explicit terms of section 156(f)(2), the term "product" as it relates to a human drug product means the active ingredient of the new drug product. The active ingredient in the approved product METVIXIA™ is methyl aminolevulinate hydrochloride, which, as an ester of the previously-approved aminolevulinic acid hydrochloride, is by statute is the same product as aminolevulinic acid hydrochloride. As noted in the above FDA letter, the active ingredient LEVULAN® had been approved for commercial marketing and use prior to the approval of the applicant's product. Furthermore, the prior approval of the active ingredient aminolevulinic acid hydrochloride in LEVULAN® by the Food and Drug Administration was under section 505 of the FFDCA, the same provision of law under which regulatory review of the product METVIXIA™ occurred. Applying the definition of "product" provided in section 156(f) to the extension requirement of § 156(a)(5)(A), applicant's product METVIXIA™ does not qualify as the first permitted marketing or use of the active ingredient. Since the approval of METVIXIA™ (methyl aminolevulinate hydrochloride) was not the first permitted marketing or use of the active ingredient thereof, the patent is not eligible for patent term extension based upon the regulatory review of METVIXIA™. See In re Fisons Pharmaceuticals Limited, 231 USPQ 305 (Comm'r Pats. 1986); aff'd, Fisons plc v. Quigg, 8 USPQ2d 1491 (DDC 1988); aff'd, 10 USPQ2d 1869 (Fed. Cir. 1988); Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (Fed. Cir. 1990).

In view of the above, the term of U.S. Patent No. 6,034,267 is not eligible for extension under 35 U.S.C. § 156 based upon the approval of the product METVIXIA™ and the application for patent term extension, filed September 22, 2004, is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7754

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7754.

Kathleen Kahler Fonda
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane
Rockwall II Rm. 1101
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Attention: Beverly Friedman

Re: METVIXIA™ (methyl amino-levulinate hydrochloride)

FDA Docket No. 2007E-0001